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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,953

08/08/2005

Steven James Burton

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

11/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,953	Applicant(s) BURTON ET AL.	
	Examiner /Venkataraman Balasubramanian/	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23, 25 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-23, 25 and 27-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/18/2008 has been entered. Claims 18-23, 25 and 27-35 are pending.

In view of applicants' response, which included amendment to claims 18, 22 and 25, the 102 rejection made in the previous office action has been obviated. However, the following rejections made in the previous office action is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-23, 25 and 27-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation in claim 18 " A compound comprising affinity ligand immobilized on support matrix " and then stating Y is same or different affinity ligand linked to triazine renders claim 18 and its dependent claims vague and unclear as to what is the affinity ligand I. As recited it is not clear whether affinity ligand is Y or it is Y linked to triazine ring. See also claim 25 and claims 27-29 for the same.

This rejection is similar to that made in the previous office action. It is not clear whether Y is an affinity ligand or the compound of formula with Y as whole is the affinity ligand.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-23, 25 and 27-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Recitation of Y is the same or different affinity ligand..." in claims 18, 25 and 27-29 has no support in the specification. Note originally Y is an aminyl group not affinity ligand. Hence, current amendment has introduced new matter.

This rejection is same as made in the previous office action. Applicants' traversal pointing to paragraph below Table 3E is not persuasive. First of all, there is no direct support for Y as affinity ligand in the specification. Specification at best states Y as aminyl in the broadest sense and paragraph below Table 3E, recites Y as various primary, secondary and tertiary amines. There is no showing that these are affinity ligand.

Secondly, there is no definition of an affinity ligand as applied to instant invention and there is no reason to believe that any amine as indistinctly defined for y choice would be an affinity ligand.

Hence, this rejection is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-23, 25 and 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowik et al., WO 01/42228.

Lowik et al., teaches several triazines compounds and their use as affinity ligands on solid supports. See pages 1-3 for description of the invention and Schemes 1-8 for various triazines made and attached to solid support. See pages 4-8 for examples 1-5 and pages 8-19 for compounds 1-53b. Especially see example 2 and various examples in Schemes (Figures 3a, 3b, 6 and 7).

Lowik et al., differs in not exemplifying compounds with diamine¹ as linker as required by instant X. But Lowik et al., includes besides exemplified piperazine, diamine as a choice. See page 4, line 4. Thus, Lowik et al., teaches use of various linker including piperazine as equivalent as linker. Hence, it would be obvious to one trained in the art to use polymer bound triazine compounds with various linker including diamine positively recited therein for affinity chromatography of proteins in view of the equivalency teaching outlined above.

Applicants' traversal to overcome this rejection is not persuasive. Applicants have argued that Lowik teaches only macromolecular compounds as affinity ligands while instant claims relates to small molecules as affinity ligand. This argument is not persuasive.

Contrary to applicants' urging, Lowik teaches small molecule ligands as well. See entire document, especially see Scheme I , left column wherein Lowik teaches non-macrocyclic compounds. See Scheme 6.

Hence, this rejection is proper and is maintained.

Claims 18-23, 25 and 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Lowik et al., WO 01/42228 and Atkinson et al., GB 2053 926.

Teachings of Lowik et al., as discussed above are incorporated herein. As noted above, Lowik et al., teach several triazines compounds and their attachment to various support materials. Lowik et al., also teaches several triazines bound matrix for affinity chromatography and Atkinson et al., teaches use of several triazines for affinity chromatography.

Atkinson et al., teaches various triazine compounds useful as affinity chromatography materials attached to a solid support. See page 1-2, especially page 2, lines 40-45. See table 1, Note Procion Red HE-3b is taught as ligand for attachment to solid support.

These two references teaches equivalency of the various triazines and their bound form for affinity chromatography. Thus, it would be obvious to one trained in the art to use polymer bound triazine compounds for affinity chromatography of proteins in view of the equivalency teaching outlined above. See *In re KSR International vs Teleflex Inc.*, 82 USPQ2d 13-85, 1397 (2007) wherein the court stated that

[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has

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good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Such is the case with instant claims. Instant claims include choices of X which are generically taught in the references cited above. It would be obvious to one trained in that that in view of the equivalency of these linker to modify such linker and arrive the triazines as affinity ligands linked to a matrix.

Applicants' traversal to overcome this rejection is not persuasive. Applicants have argued that Lowik teaches only macromolecular compounds as affinity ligands while instant claims relates to small molecules as affinity ligand. This argument is not persuasive.

Contrary to applicants' urging, Lowik teaches small molecule ligands as well. See entire document, especially see Scheme 1, left column wherein Lowik teaches non-macrocylic compounds. See Scheme 6.

Thus, based on the combined teaching of Lowik and Atkinson and the guidance provided therein, it would be obvious to one trained in the art to make matrix bound triazines bearing various amino groups as affinity ligands for proteins and expect them to have the use for protein separation, purification etc.

Hence, this rejection is proper and is maintained.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571)

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272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624